I. The Office Action

The November 14, 2005 office action in this application (the "Office Action"):

- 1. rejected claims 1-2, 4-5 and 13 under 35 U.S.C. section 112, first paragraph;
- 2. rejected claims 1-5 and 13 under 35 U.S.C. section 112, second paragraph over WO 94/24155, and;.
- 3. provisionally rejected claims 1-5 and 13 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 and 16-17 of copending application 11/072,050.

Applicants respond to the Office Action as follows.

II. Section 112(1) Rejection

The Office Action rejected claims 1-2, 4-5 and 13 under 35 U.S.C. section 112, first paragraph. The Office Action states that the specification is enabling for methods limited to use of soy (claim 3).

Respectfully the rejection is in error and should be withdrawn. Note that page 18, lines 26-29 disclose use of various non-animal protein sources. Additionally, Example 3 (entitled "Preparation of an animal product free fermentation media for Clostridium Botulinum") at page 30, lines 20-27 discloses use of soy, yeast, malt and corn as non-animal sources of protein (i.e. nitrogen) in the fermentation medium. Clearly a person of ordinary skill in the field with, for example, the disclosure of Example 3 would be able to practice the claimed invention by use or at least the Example 3 vegetable protein sources.

Thus, limiting enabled scope to a fermentation medium which must include soy would appear to deprive the inventor of the full scope of his disclosed invention.

Hence, all claims have been limited to a fermentation medium which include a soy, yeast, malt or corn. For these reasons the rejection should be withdrawn.

III. Section 112(2) Rejection

The Office Action rejected claims 1-5 and 13 under 35 U.S.C. section 112(2). The rejection has been addressed as follows:

- 1. Claims 1-5 and 13 were rejected for use of the phase "substantially free". This phrase has been amended in the claims to "not more than about 1 weight percent". Support for this claim limitation can be found at at least page 18, lines 15-16 and page 21, lines 8-11.
- 2. Claims 1-5 and 13 were rejected for use of the phase "animal derived product". This phrase has been amended in the claims to "an animal derived product selected from the group consisting of an immunoglobulin, meat product, meat digest, meat by product, milk, dairy product, dairy digest, blood pooled product, blood derived product and animal derived protein".

Support for these claim limitations can be found in the specification as follows:

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"immunoglobulin": page 15, line 14;
"meat digest": page 15, line 14;
"meat product": page 15, line 17;
"meat by product": page 15, lines 14 and 17;
"milk": page 15, line 14;
"dairy product": page 15, line 14;
"dairy digest": page 15, line 14-15;
"blood pooled product": page 15, line 5;
"blood derived product": page 15, lines 4-5;
"animal derived protein": page 15, line 13.
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3. Claims 2 and 3 were rejected for use of the phrase "derived from". Claims 2-3 have been cancelled and the phrase "obtained from a vegetable" has been used in claims 1 and 13, as suggested on page 8 of the Office Action.

For these reasons the rejection should be withdrawn.

IV. Double Patenting

The Office Action provisionally rejected claims 1-5 an 13 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 and 16-17 of copending application serial number 11/072,050.

An executed terminal disclaimer is enclosed so the provisional rejection should be withdrawn.

V. New Claims 14-21

New claims 14-21 are supported by the specification at least as follows:

- 1. Claim 14: page 15, lines 21-23.
- 2. Claim 15: page, lines 21-23 and page 28, line 28.
- 3. Claim 16: page 15, lines 23-29.
- 4. Claim 17 is a combination of claims 1 and 15.
- 1. Claim 18: page 15, lines 21-23.
- 2. Claim 19: page, lines 21-23 and page 28, line 28.
- 3. Claim 20: page 15, lines 23-29.
- 4. Claim 21 is a combination of claims 13 and 1 and 19.

VI. Cancelled Claims

Applicants hereby cancel claims 2-3 without prejudice to further prosecution at a later date.

VII. Conclusion

All issues raised by the Office Action have been addressed. Examination and allowance of claims 1, 4-5 and 13-21 is requested.

Respectfully Submitted,

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Date: December 2, 2005

CERTIFICATE OF EXPRESS MAIL UNDER 37 C.F.R. § 1.10

I hereby certify that this Transmittal Letter, Response to Notice of Non-Compliant Amendment, Response to Office Action and the documents referred to as enclosed therein are being deposited with the United States Postal Service on this date **December _2**, 2005 in an envelope as "Express Mail Post Office to Addressee" Mailing Label number EV 616 126 328 US addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

<u> Adriane Giberson</u>

Name of person mailing paper

Signature of person-signing paper